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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO.       |
|---|-------------|----------------------|-----------------------------------|------------------------|
| 10/709,572  | 05/14/2004  | Itzhak Bentwich      | 050992.0202.01USCP                | 3571                   |
| 37808   | 7590        | 05/21/2009           |                                   |                        |
| ROSETTA-GENOMICS<br>c/o PSWS<br>700 W. 47TH STREET<br>SUITE 1000<br>KANSAS CITY, MO 64112 |             |                      | EXAMINER<br>WOLLENBERGER, LOUIS V |                        |
|   |             |                      | ART UNIT<br>1635                  | PAPER NUMBER           |
|   |             |                      | MAIL DATE<br>05/21/2009           | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                       |  |  |
|------------------------------|---------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/709,572  | <b>Applicant(s)</b><br>BENTWICH ET AL. |  |
|                              | <b>Examiner</b><br>Louis Wollenberger | <b>Art Unit</b><br>1635                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 25, 26, 29, 30 and 35-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25, 26, 29, and 30 is/are allowed.
- 6) ☒ Claim(s) 35-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/10/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application/Amendment/Claims***

Applicant's response filed 3/10/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 9/10/2008 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

With entry of the amendment filed on 3/10/2009, claims 25, 26, 29, 30, and 35-38 are pending and under consideration.

### ***Election/Restrictions***

In the reply filed 2/25/08, Applicant elected, without traverse, SEQ ID NO:159.

Applicant's previous amendment to claim 30, deleting references to all previously recited SEQ ID NOs except SEQ ID NO:6821380 is considered to represent constructive election of SEQ ID NO:6821380.

### ***Claim Rejections - 35 USC § 101 and 112, First Paragraph—withdrawn***

The rejection of Claims 25, 26, 29, 30, and 35-38 under 35 U.S.C. 101 and 112 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible asserted utility, or a well established utility is withdrawn in view of the totality of evidence of record.

*Specification*

The application contains disclosure entirely outside the bounds of the allowed claims. Applicant is required to modify the brief summary of the invention and restrict the descriptive matter so as to be in harmony with the claims (MPEP § 1302.01).

In the instant case the specification incorporates by reference several large tables, Tables 1-14, submitted to the Office in the form of compact discs, which, altogether, are said by applicant to contain several thousand kilobytes of information, the large majority of which is not pertinent to the claimed invention: SEQ ID NO:159 and 6821380. See paragraph 24 of the specification.

Using the conversion factor set forth in 37 CFR 1.52(f)(1), the electronic information contained in Tables 1-14 represents tens if not hundreds of thousands of sheets of additional disclosure beyond the approximately 254 pages of paper copy specification filed therewith. A review of Tables 1-14 finds the tables disclose information directed to hundreds of thousands of different nucleotide sequences that have no disclosed relation to the claimed sequences. Moreover, a review of the paper portion of the specification fails to find any information disclosing how to use the instantly claimed sequences. The paper portion discloses information general to bioinformatically isolated sequences and no information specific to the claimed sequence(s) themselves.

In addition to the requirement under MPEP 1302.01, Applicant is required under 37 CFR 1.52(e)(5) to amend the specification to include in the paper portion of the specification all descriptive matter pertinent to SEQ ID NO:159 and 6821380 that was previously submitted in tables on compact disc. Amendments to the specification and submission of substitute

specifications, including statements to be submitted therewith, must comply with 37 CFR 1.121 and 1.125.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As amended on 3/10/2009, the claims recite vectors comprising “a heterologous sequence” consisting of any of the nucleic acids of claims 25, 26, 29, or 30.

The term “heterologous” is defined neither by the claims nor the specification. The ordinary and customary meaning of the term "heterologous" according to one online dictionary (Merriam-Webster) is "derived from a different species." Thus, the heterology of a sequence can be determined only by comparison to another sequence. In the instant case, the claims do not provide a context by which to determine the heterology of a sequence because the claims do not clearly state what sequences are being compared or what reference is to be used in determination of heterology. Claims 25 and 29 in particular embrace a multitude of possible DNA and RNA sequences. Claims 26 and 30 are much narrower in scope, but include the language “is of the sequence of,” the meaning of which is not entirely clear but which would appear to embrace more than simply SEQ ID NO:159 and 6821380.

Therefore, while it may be applicant's intention to distinguish between vector elements required for vector function and the nucleic acid insert, neither the claims nor the specification

Art Unit: 1635

clearly define how and to what degree the sequences of claims 25, 26, 29, and 30 must differ from a vector sequence to be considered “a heterologous sequence” as currently recited by the claims. Thus, the metes and bounds of the claims are unclear since it cannot be determined which sequences are specifically excluded or included by the claims.

***Claim Rejections - 35 USC § 112, first paragraph (new matter)***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendment to the claims submitted on 3/10/2009, introduces the limitation “a heterologous sequence” and “wherein the heterologous sequence consists of” into dependent claims 35-38.

MPEP 2163, Section II, Part A, states in part that there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. The purpose of the written description requirement is "to ensure that the inventor had possession,

as of the filing date of the application relied on, of the specific subject matter later claimed by him." MPEP 2138.05, I.

In the instant case, Applicant points to paragraph 27 in the specification as support. However, a review of this passage and the application as a whole fails to find clear, antecedent support for this terminology. There is no disclosure describing 1) isolated heterologous sequences, or 2) vectors comprising heterologous sequences. The heterology or homology of any given sequence depends on what it is being compared to. The instant application fails to identify which species of the multitude of sequences now claimed qualify as heterologous sequences, nor is there any disclosure of a sequence or core element common to "a heteroglous sequence." Further, there is no disclosure teaching or suggesting that all sequences embraced by each of claims 25, 26, 29, and 30 are heterologous in the context of any vector. The term "heterologous" does not appear in the application as filed, and applicant fails to show how the current language is explicitly, implicitly, or inherently supported by the application as filed.

Accordingly, the instant claims as a whole are rejected for lack of written description support because one of skill would not recognize applicant was in possession of the invention as now claimed at the time of filing.

### ***Conclusion***

Claims 25, 26, 29, and 30 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 1635

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/  
Primary Examiner, Art Unit 1635  
May 19, 2009